Anthony Davis

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He has built a company-wide quality system from nothing four times, across every GxP.

COMPLEXANT — PARTNERS —

Signature value

Builds the quality system you need at the stage you are actually at, not the one a larger company would recognize. Four builds from nothing means knowing what to leave out, which is harder than knowing what to put in and far more expensive to get wrong. Then holds it through the transitions that break systems: first filing, first launch, new modality, new regulator.

Scale

4	company-wide quality systems built from nothing, plus R&D quality systems at a fifth company
5 GxPs	GMP, GCP, GLP, GDP, and GVP owned in a single seat
Ph 1-C	Phase 1 through NDA, launch, and commercial manufacture

Results

- Corporate quality systems designed and implemented from first build at Affinia Therapeutics, iTeos Therapeutics, Cullinan Oncology, and Dicerna Pharmaceuticals
- Medical device QMS established inside an existing QMS within 6 months to support an NDA filing and commercial launch
- Company representative to regulators during inspection, and leader of international audits of sites, CMOs, CROs, and laboratories
- Environments from venture-backed clinical-stage biotech and contract testing laboratory to public commercial-stage and large multinational biopharmaceutical

Industries and modalities

- **Therapeutics:** oncology, rare and genetic disease, gene therapy, oligonucleotide therapeutics
- **Modalities:** sterile injectables, biologics, gene therapies, solid dose, OTC drugs, medical devices
- **Specialized:** high-complexity testing laboratory operations under CAP, CLIA, OSHA, HIPAA, and GLP; pharmacovigilance and drug safety oversight

Executive profile

Has built a company-wide quality management system from nothing four times: at Affinia Therapeutics, iTeos Therapeutics, Cullinan Oncology, and Dicerna Pharmaceuticals. Building one is common. Building four, each sized to a different pipeline at a different stage, is how you learn what a quality system genuinely needs to contain when there is no template to copy and no room to over-build. Carries GMP, GCP, GLP, GDP, and GVP in a single seat rather than specializing in one, from Phase 1 to commercial production. Has worked both sides of the audit table: leading international audits of sites, CMOs, CROs, and laboratories, and representing the company when the regulator is the one asking.

Core expertise

Quality system build and ownership. Design and implementation of company-wide Corporate Quality Systems supporting early- and late-stage development, including cross-functional SOPs, team structure, policies and procedures, quality metrics and KPIs, and phased sizing of the system to pipeline maturity.

Cross-GxP leadership. Ownership of GMP, GCP, GLP, GDP, and GVP quality in a single organization, covering investigations and deviations, CAPA, change control, document management, complaints, batch and CMO lot release, validation, and risk management under 21 CFR Parts 210/211, 50, 312, 600, and 820, ICH guidance, EU Directives 2001/20/EC and 2003/94/EC, EudraLex Volume IV, and PIC/S.

Audit and inspection leadership. Leadership of international audits across investigator sites, quality systems, clinical and medical operations, clinical trial management and drug safety systems, regulatory submissions, labeling, CMOs, CROs, testing laboratories, and suppliers, and direct representation of the company during regulatory inspection.

Vendor oversight, training, and culture. Creation of supplier and vendor management programs, oversight of external providers supporting clinical operations, pharmacovigilance, regulatory affairs, and quality assurance, development of competency-based GxP training programs, and assisting Finance with SOX compliance and internal controls.

Global regulatory and audit leadership

Leads and supports inspections and audits under the frameworks applicable to each program: as the company representative before regulatory authorities, across clinical investigator sites Phase I through Phase IV for GCP compliance, and across CMOs, CROs, testing laboratories, suppliers, and internal GxP processes, departments, and IT systems. Laboratory operations audited under CAP, CLIA, OSHA, and HIPAA.

Digital and quality systems leadership

Led selection, implementation, and project management of validated quality software covering change control, document management, audit, training, and complaints, and served as quality information technology lead with oversight of internal and external IT system audits. Platforms include Veeva, TrackWise, MasterControl, Dot Compliance, LIMS, MES, CTMS, SAP, and Oracle. Uses AI as a tool, verifies what it produces, and keeps the decision, with the human in the lead, not just the loop; applies data integrity to adopt innovation, including AI, compliantly.